

UNITED STATES PATENT
AND TRADE OFFICE,
Washington, DC, July 30, 2002.

Hon. ORRIN HATCH,
U.S. Senate,
Washington, DC.

DEAR SENATOR HATCH: In a few months, the United States Patent and Trademark Office (USPTO) will celebrate its 200th year in existence. During that time, we have been the only Federal agency charged with administering this Nation's patent laws and determining whether inventions are patentable. USPTO plays a critical role in promoting and protecting intellectual property and the work of our Agency helps to stimulate American innovation and investment.

At your request, USPTO is providing its views on the advisability of the changes in patent laws in S. 812, the Greater Access to Affordable Pharmaceuticals Act. This letter is intended to inform you of our objections to the current language in S. 812.

First, in some cases, S. 812 would forfeit unnecessarily the core right of patent holders—the right to exclude others from practicing the invention for the entire patent term. After years of research and development and significant investment, the patent right is extinguished for the mere failure to satisfy an administrative task or respond in a timely manner. For example, if a patent holder fails to list the patent with the Food and Drug Administration within a certain time period, the patent is invalidated. Furthermore, if a patent owner fails to bring an infringement action within 45 days of receiving notice (also known as 'Paragraph IV') from a drug manufacturer that the patent is invalid or not infringed by the generic drug, then the patent right is forfeited. In this circumstance, the patent owner is barred from ever bringing an infringement case in connection with the generic drug at issue.

Second, we are concerned with the bill's disparate treatment of patents depending on issue date. The Hatch-Waxman Act gives a patent holder an automatic 30-month stay to defend a challenge to the patent by a generic drug company. S. 812 would apply this 30-month stay only to patents that issue within 30 days of the new drug application approval. This limitation is arbitrary and unrealistic. The timing of issuance bears no relation to the importance of innovation. Moreover, the patent applicant often has no control over when a patent issues. Therefore, affording certain benefits to patents that issue only within a certain time frame would be unworkable and unjust.

Finally, USPTO believes it is vital to consider each patent rigorously and uniformly to determine whether the application satisfies the standards of patentability. All patent applications are examined with equal scrutiny and all patents must satisfy the same criteria of utility, novelty, and non-obviousness before they are issued. Each pharmaceutical patent, like all other patents, is entitled to a presumption of validity and should be judged accordingly.

USPTO does recognize that some changes to current law may be necessary to encourage appropriate access to generic substitutes and prevent abuses of the patent laws. But S. 812 clearly is not the answer. In fact, this bill would likely do the opposite of what its title suggests—by limiting access to cutting-edge drugs, decreasing innovation, and ultimately harming the quality of treatments available to patients.

Before considering any future legislative efforts, we should applaud the success of the time-tested Hatch-Waxman Act and respect the delicate industry balance it forged. In all cases, any changes should incorporate the expertise of the Committees on the Judiciary of Congress, in addition to the appro-

priate Government agencies. Only through a carefully conducted analysis can a result be reached that benefits consumers while promoting the progress of science and innovation.

I hope this information is helpful and I would welcome the opportunity for consultation on future endeavors.

Sincerely,

JAMES E. ROGAN,
Under Secretary and Director.

AMERICA MEMORIALIZES TWO MORE VIETNAM WAR HEROES

Mr. LOTT. Mr. President, I rise today in remembrance of a fellow Mississippian, Fred C. Cutrer Jr. and his navigator Leonard L. Kaster, who died serving their country during the Vietnam War. Captain Fred C. Cutrer Jr. was a pilot on a B57 Canberra Bomber, and during his service for his country, he became instantly known around his base as a loving husband and an immensely proud father of two sons. He would often be found showing pictures of his family to his friends and squadron. Fred was also courteous and friendly, exemplifying the character of a true southern gentleman. Jimmy Speed, a childhood buddy described his charming character by stating,

I use to call him good-humor man. He was a very smart man, and people liked him immediately. I always felt that if he had gotten to the ground alive, those people wouldn't have hurt him because he was so likeable and friendly that he would have fit into any crowd.

On August 6, 1964 Cutrer and 1Lt. Leonard L. Kaster, unknowingly flew the skies for their last time. They were flying over South Vietnam, North East of Tan Son Nhut, and according to Defense Intelligence data, their airplane came under heavy fire from Viet Cong forces, causing them to crash and explode near the Sang Dong Nai River in Long Khan Province. Both men were classified "Killed in Action, Body Not Recovered," and Cutrer was promoted to the rank of Major.

In the spring of 1997, the Department of Defense, with the help of a Vietnamese native, helped bring closure to Cutrer's family by finding Cutrer's dog tag and aircraft identification plate that had been buried one meter beneath the surface of a jungle bog. This discovery led to the declaration of these men's ceremonial burial for June 6, 2002, with full military honors. I am thankful to say that both of these men, nearly forty years following their patriotic death for their country, now lay buried in Arlington National Cemetery.

Both the Cutrer and Kaster families flew from Mississippi to attend the ceremony, and Air Force General Frank Faykes presented flags to the families of both men. Buried alongside Cutrer is his wife, Shirley, who was killed in an automobile accident four years ago. The children were pleased to see their father properly honored as a hero and their mother rightfully buried beside him.

American troops have a slogan stating, "We leave no man behind." I be-

lieve this manifests the pride and patriotism of our troops. Cutrer's sister, Lillie Cutrer Gould, promised her younger brother that if anything were to happen to him in Vietnam, then she would bring him back home. Not too many days ago, Mrs. Gould successfully achieved her promise to her brother, and America again exercised its duty and commitment to its soldiers.

I salute John C. Cutrer Jr. and Leonard L. Kaster for serving their country and helping make America a better and safer place to live. I am thankful that I reside in a country where we take pride in our soldiers, and we carry a strong commitment never to forget their courageous acts nor to leave anyone behind. I want to thank God for allowing John and Shirley Cutrer to eternally lay side-by-side in Arlington's National Cemetery, and I want to thank America for again making me proud of our citizens. I know my colleagues will join me in memorializing and commending the lives of John C. Cutrer Jr. and Leonard L. Kaster, two American heroes.

REMEMBERING MR. JOHN M. McGEE

Mr. LOTT. Mr. President, I rise today to pay proper tribute to Mr. John M. McGee, a devoted husband, father, and grandfather as well as a memorable American patriot. John was born in Brookhaven, MS on September 16, 1933, and in February 23, 2002, John passed away as a result of a sudden heart attack. In his high-school years, John was blessed with speed and athleticism that contributed to his becoming an extraordinary football player and an excellent athlete. John's athleticism led him to set the state record in the 100-yard dash. John attended my alma mater, the University of Mississippi, where he played football for the Ole Miss Rebels. John's patriotism towards his country convinced him to interrupt his education at Ole Miss and enlist with the U.S. Navy where he served on the destroyer tender *Shenandoah* and the destroyer *Willard Keith*. During his duty in active service, John took part in the decisive Inchon invasion commanded by General Douglas MacArthur.

John went on to earn his bachelor's degree in engineering from the Armed Forces Institute. After an honorable discharge, he pursued his career in engineering until 1966 when he accepted a job with the Department of Defense where he conducted operations in Vietnam, Cambodia, Laos, and Thailand until 1969. During John's service in Vietnam, he discovered and exposed extensive corruption in American military operations. The Governmental Accounting Office confirmed these allegations, and John's discovery revealed the theft of 5.5 million gallons of fuel that had been originally intended for U.S. Military forces but had been penetrated and used by the enemy. John's inquiry helped save the lives of many